#### STATE OF VERMONT

#### HUMAN SERVICES BOARD

In re	)	Fair	Hearing	No.	B-11/08-504
	)				
Appeal of	)				

### INTRODUCTION

The petitioner appeals a decision by the Office of

Vermont Health Access (OVHA) denying prior authorization for

payment of the prescription drug Subutex by the Vermont

Health Access Program (VHAP). The issue is whether the

petitioner has demonstrated that he meets the prior

authorization requirements for VHAP payment for Subutex.

The following decision is based on the evidence adduced at fair hearing.

# FINDINGS OF FACT

- 1. The petitioner is a thirty-year-old male who is currently unemployed and in receipt of unemployment compensation benefits. Petitioner receives VHAP.
- 2. The petitioner receives treatment for opiate addiction. As part of his treatment, petitioner is prescribed Subutex. Petitioner is seeking VHAP payment for Subutex. Petitioner presently pays directly for Subutex.

Petitioner has been prescribed Subutex for approximately eighteen months. In the past, his private insurance paid for the medication. The State also paid for Subutex before the State made a change regarding prior authorization for Subutex.

- 3. The State of Vermont maintains a list of preferred drugs that are covered by Medicaid and VHAP. Suboxone is listed as the preferred drug for treatment of opiate addiction or chemical dependency. Prior authorization is necessary for both Suboxone and Subutex. However, there are more stringent requirements for Subutex because the drug has been diverted to street usage.
- 4. Dr. M.F., petitioner's treating doctor for opiate addiction, submitted a request for prior authorization on September 2, 2008 for Subutex noting that petitioner had an allergic reaction to Suboxone. Medical records documenting the allergic reaction were not submitted with the request. OVHA staff spoke to Dr. M.F.'s office and were told that petitioner experienced nausea, vomiting and diarrhea when he tried Suboxone in February and March 2007. OVHA did not categorize these adverse reactions as allergic reactions.
- 5. OVHA sent petitioner and Dr. M.F. a Notice of Decision denying prior authorization on September 8, 2008.

6. Petitioner filed a Notice of Appeal asking for an internal appeal on September 30, 2008. An internal appeal was held on October 7, 2008. Petitioner represented himself at the internal appeal. Dr. E.C., OVHA assistant medical director, appeared at the internal appeal.

At the internal appeal, petitioner stated that use of Suboxone caused migraines and nausea. Petitioner had not tried any anti-nausea medications. There was no medical documentation of migraines. The record was held open to allow further information from Dr. M.F.

- Dr. E.C. spoke with Dr. M.F.'s office. There was verification of migraines but not gastro-intestinal side effects. Dr. E.C. upheld the denial stating that migraines are not a reportable side effect in the medical literature. She suggested that petitioner use Suboxone for a trial period so his doctor could document an allergic reaction.
- 7. OVHA sent petitioner a Notice of Decision dated October 16, 2008. Petitioner filed a request for fair hearing on November 5, 2008.
- 8. A fair hearing was commenced on December 11, 2008. The petitioner was given a copy of OVHA's file. The hearing was continued until January 13, 2009 to allow petitioner time to arrange for Dr. M.F. or one of his staff to testify by

telephone at the January 13, 2009 hearing. Petitioner was informed on December 11, 2008 and through a memorandum dated December 15, 2008 that he needed testimony or information from his doctor's office documenting that he had an allergic reaction to Suboxone.

9. The hearing reconvened on January 13, 2009. Dr. E.C. testified and explained that OVHA required medical documentation from a treating doctor setting out why a particular patient had been unable to tolerate Suboxone after a legitimate trial of that drug. She testified that migraine headaches were not an allergic reaction.

Petitioner testified. Petitioner stated that Dr. M.F. and staff from his office would be unable to testify by telephone because of their work schedule. Petitioner testified that he had migraine headaches when he tried Suboxone in 2007. Petitioner also testified that he has a history of headaches which predate his use of Suboxone.

Petitioner was given an additional two weeks to submit written documentation from Dr. M.F.'s office. Petitioner has not done so.

10. The literature on Suboxone indicates that headaches and nausea are possible adverse reactions that can be treated; the literature does not include migraine headaches or nausea among the listed allergic reactions.

### ORDER

OVHA's decision to deny prior authorization for payment of Subutex is affirmed.

## REASONS

Prior authorization is required for certain medical procedures and medications. The purpose of prior authorization is, in part, to assure that treatment options fall within accepted parameters. M 106.1. In terms of treatment for chemical dependency, OVHA has developed protocols in cases where the use of Suboxone<sup>2</sup> (naloxene) is contraindicated and Subutex should be prescribed instead.

OVHA uses the following criteria for Subutex:

A. What is the diagnosis or indication for the requested medication?

Opiate dependency, ask question B

<sup>&</sup>lt;sup>1</sup> See materials from the Substance Abuse & Mental Health Services Administration, U.S. Department of Health & Human Services. http://buprenorphine.samsha.gov/bwns\_locator/index. html, www.fda.gov/cder/drug/infopage/subutex\_suboxone/default.htm.

<sup>2</sup> Prior authorization is required for Suboxone. Suboxone has only been approved for treatment of opiate addiction; its usage is heavily regulated by the federal government.

Other: review request with a pharmacist (Suboxone will not be approved for the treatment of pain)

B. Does the prescriber have an "x" DEA license (and is listed on the Vermont X-prescriber list)?

Yes: ask question D. No: ask question C.

C. Does the prescriber have an "x" DEA (and is <u>not</u> <u>listed on the Vermont X-prescriber list</u> (other state, etc.)?

Yes: document below and ask question D... No: deny

- D. Is the patient pregnant? Delivery date\_\_\_\_\_ Yes: approve 1 month past anticipated delivery date... No: ask question E
- E. Does the patient have an allergy to naloxene? Yes: forward to clinical review (Note: medical records documenting a true allergy to naloxene must be submitted)

No: denv

The petitioner has the burden to show that Subutex is medically necessary in his case. The medications to treat chemical dependency are heavily regulated to ensure proper usage. This is particularly true in the case of Subutex due to the danger of diverting the drug to the street. OVHA has adopted a strict protocol to determine when Subutex should be authorized.

The petitioner has not submitted sufficient medical documentation that he is allergic to Suboxone although he has been given the opportunity to do so. No written records have

been submitted from petitioner's doctor. The petitioner can always reapply for prior authorization if he attempts a trial period of Suboxone and his medical providers can document an allergic reaction.

Based on the above evidence, OVHA's decision to deny prior authorization for Subutex is affirmed. 3 V.S.A. § 3091(d), Fair Hearing Rule 1000.4(D).

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